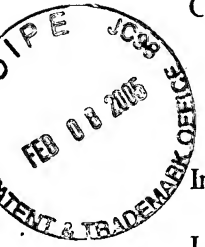


Attorney Docket No.: 330310.00103
Customer No. 27160

U.S. Patent Application No.
10/669,250



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Leland SHAPIRO

Application No.: 10/669,250

Filed: September 25, 2003

For: INHIBITORS OF SERINE PROTEASE
ACTIVITY, METHODS AND
COMPOSITIONS FOR TREATMENT
OF NITRIC OXIDE INDUCED
CLINICAL CONDITIONS

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: Group Art Unit: 1645
:
: Examiner: Not Yet Assigned
:
: Confirmation No.: 3190
:
: Atty. Dkt. No.: 330310.00103

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 8, 2005

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. §1.56 and in accordance with the practice under 37 C.F.R. §§1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B. Please note that these documents were all considered in related application 09/518,097, filed March 3, 2000; now U.S. Patent No. 6,489,308, issued December 3, 2002. For the convenience of the Examiner a partial copy of the above patent with the listed references is enclosed. The citation numbers have been marked on the patent for ease of comparison.

FORMAL MATTERS

In accordance with 37 C.F.R. § 1.97(b)(3), since a first Official Action on the merits of the subject application has not yet been issued, neither a certificate, petition nor payment of a fee is believed to be required for this Information Disclosure Statement. However, the Commissioner is hereby

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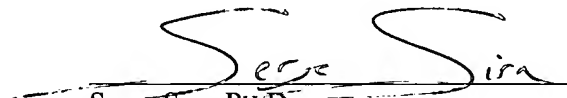
authorized to charge any fee which may be required in connection with this paper to Deposit Account No. 50-1710.

CONCLUSION

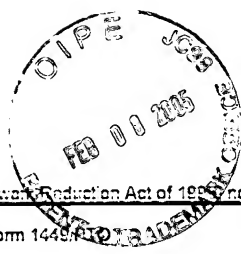
It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned indicating that such information has been considered.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,


Serge Sira, PH.D.
Attorney for Applicant
Registration No. 39,445

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3963
(202) 625-3500



PTO/SB/03A (03-03)

Approved for use through 07/31/2006. CMB 0651-0331

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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(Use as many sheets as necessary)

Complete if Known

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 1 of 17

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US- 4,021,472 A	05/1977	Fujii et al.	
	2	US- 4,051,842 A	10/1977	Hazel et al.	
	3	US- 4,140,122 A	02/1979	Kuhl et al.	
	4	US- 4,224,342 A	09/1980	Fujii et al.	
	5	US- 4,283,418 A	08/1981	Fuji et al.	
	6	US- 4,310,533 A	01/1982	Uegai et al.	
	7	US- 4,383,529 A	05/1983	Webster	
	8	US- 4,629,567 A	12/1986	Bollen et al.	
	9	US- 4,657,763 A	04/1987	Finkelstein	
	10	US- 4,668,504 A	05/1987	Kahan et al.	
	11	US- 4,711,848 A	12/1987	Insley et al.	
	12	US- 4,713,224 A	12/1987	Tamhankar et al.	
	13	US- 4,732,973 A	03/1988	Barr et al.	
	14	US- 4,760,130 A	07/1988	Thompson et al.	
	15	US- 4,788,603 A	11/1988	Fujimura et al.	
	16	US- 4,829,052 A	05/1989	Glover et al.	
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	18	US- 4,843,094 A	06/1989	Imaki et al.	
	19	US- 4,889,723 A	12/1989	Kim et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	20	WO 94/07525	04/1994			
	21	WO 95/28422	10/1995			
	22	WO 95/34538	12/1995			
	23	WO 96/12021	04/1996			
	24	WO 96/14067	05/1996			
	25	WO 97/03679	02/1997			

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Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 2 of 17

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		Number-Kind Code ² (if known)			
	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
	29	US- 5,077,428 A	12/1991	Imaki et al.	
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	31	US- 5,157,019 A	10/1992	Glover et al.	
	32	US- 5,166,134 A	11/1992	Lezdey et al.	
	33	US- 5,175,253 A	12/1992	Fallon et al.	
	34	US- 5,214,191 A	05/1993	Kirschenheuter et al	
	35	US- 5,216,022 A	06/1993	Oleksyszyn et al.	
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	37	US- 5,247,084 A	09/1993	Imaki et al.	
	38	US- 5,399,346 A	03/1995	Anderson et al.	
	39	US- 5,416,191	05/1995	Cheronis et al.	
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	41	US- 5,432,178 A	07/1995	Nakai et al.	
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	45	WO 97/09346	03/1997			
	46	WO 97/09347	03/1997			
	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
	50	WO 97/24339	07/1997			

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First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 3 of 17

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	51	US- 5,486,470 A	01/1996	Darke et al.	
	52	US- 5,489,593 A	02/1996	Palmer et al.	
	53	US- 5,504,094 A	04/1996	Nakane et al.	
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	61	US- 5,604,201 A	02/1997	Thomas et al.	
	62	US- 5,610,140 A	03/1997	Goodfellow et al.	
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	64	US- 5,614,555 A	03/1997	Nakai et al.	
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	70	WO 97/31937	09/1997			
	71	WO 97/33996	09/1997			
	72	WO 97/37969	10/1997			
	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
	75	WO 97/49679	12/1997			

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First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 4 of 17

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
	77	US- 5,665,589 A	09/1997	Harris et al.	
	78	US- 5,700,779 A	12/1997	Goodfellow et al.	
	79	US- 5,710,026 A	01/1998	Sprecher	
	80	US- 5,712,117 A	01/1998	Sprecher	
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	82	US- 5,750,506 A	05/1998	Goodfellow et al.	
	83	US- 5,759,548 A	06/1998	Bathurst et al.	
	84	US- 5,780,009 A	07/1998	Karatzas et al.	
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	87	US- 5,804,594 A	09/1998	Murad	
	88	US- 5,807,829 A	09/1998	Gyorkos et al.	
	89	US- 5,811,241 A	09/1998	Goodfellow et al.	
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	91	US- 5,834,431 A	11/1998	Stewart et al.	
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

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	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
	102	US- 5,863,899 A	01/1999	Cheronis et al.	
	103	US- 5,869,455 A	02/1999	Gyorkos et al.	
	104	US- 5,874,424 A	02/1999	Batchelor et al.	
	105	US- 5,874,585 A	02/1999	Gyorkos et al.	
	106	US- 5,891,852 A	04/1999	Gyorkos et al.	
	107	US- 5,914,342 A	06/1999	Maurer et al.	
	108	US- 6,127,356 A	10/2000	Crapo et al.	
	109	US- 6,140,116 A	10/2000	Dinsmore et al.	
	110	US- 6,235,714 B1	05/2001	Paul et al.	
	111	US- 6,323,219 B1	11/2001	Costanzo	
	224	US- 5,281,617 A	01/1994	Kirschenheuter et al	
	225	US- 5,314,910 A	05/1994	Kirschenheuter et al	
	226	US- 5,376,655 A	12/1994	Imaki et al.	
		US-			
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	112	WO 98/23565	06/1998			
	113	WO 98/24806	06/1998			
	114	WO 98/46597	10/1998			
	115	WO 98/49190	11/1998			
	116	WO 98/50342	11/1998			
	117	WO 98/50420	11/1998			

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
	121	WO 00/52034	09/2000			

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				Application Number	10/669,250
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	7	of	17	Attorney Docket Number	330310.00103

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	122	Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacyclatin, a proteinase inhibitor in rice, against herpes simplex virus type I in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
	123	Auerswald et al., "Recombinant leech-derived trypsin inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).	
	124	Avril LE, Di Martino-Ferrer M, Barin F, Gauthier F., "Interaction between a membrane-associated serine proteinase of U-937 monocytes and peptides from the V3 loop of the human immunodeficiency virus type I (HIV-1) gp120 envelope glycoprotein", FEBS Lett, 317(1-2):167-72 (Feb. 8, 1993).	
	125	Beal, M.F., "Mitochondria, Free Radicals, and Neurodegeneration", Curr. Opin. Neurobiol., 1996, 6, 661-666.	
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				Application Number	10/669,250
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
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	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).	
	134	Holwerda BC. Herpesvirus proteases: targets for novel antiviral drugs. Antiviral Res Jun. 1997;35(1):1-21.	
	135	Inocencio et al., "Endoprotease activities other than furin and PACE4 with a role in processing of HIV-1 gp160 glycoproteins in CHO-K1 cells", J Biol Chem, 272(2):1344-8 (1997).	
	136	Jabs, Thorsten, "Reactive Oxygen Intermediates as Mediators of Programmed Cell Death in Plants and Animals", Biochem Pharmacol 1999, 57, 231-245.	
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	139	Kido H, Niwa Y, Beppu Y, Towatari T. Cellular proteases involved in the pathogenicity of enveloped animal viruses, human immunodeficiency virus, influenza virus A and Sendai virus. Adv Enzyme Regul 1996;36:325-47.	
	140	Best, P.J.M., et al., Arterioscler Thromb Vasc Biol 1999, 19, 14.	
	141	Lomas DA, Elliott PR, Carrell RW. Commercial plasma alphas-1-antitrypsin (Prolastin) contains a conformationally inactive, latent component. Eur. Respir J Mar. 1997;10(3):672-5	

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	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
	143	Miranda et al., "Isolation of the human PC6 gene encoding the putative host protease for HIV-1 gp160 processing in CD4+ T lymphocytes", Proc Natl Acad Sci U S A, 93(15):7695-7700 (1996).	
	144	Molle W. et al. in J Immunol 1997, 159, 3555.	
	145	Morel, J. B. and Dangle, J.L., Cell Death Differ 1997, 4, 67 1.	
	146	Ohnishi et al., "A furin-defective cell line is able to process correctly the gp160 of human immunodeficiency virus type I", J Virol, 68(6):4075-99 (1994).	
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	148	Pellegrini A, Thomas U, Franchini M, Stockli M, Klauser S, Hunziker P, von Fellenberg R. Identification of an aprotinin antiviral domain. FEBS Lett May 16, 1994;344(2-3):261-5.	
	149	Schwartz, et al., "Antiviral activity of the proteasome on incoming human immunodeficiency virus type I", J Virol, 72(5):3845-50 (1998).	
	150	Sichko ZhV, Koslova OL. Experience in treating herpetic infection with trypsin [Article in Russian]. Vrach Delo Mar. 1991;86-9.	
	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.	

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				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
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	152	Cilberto et al., 1985, Cell, 41:531-540.	
	153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
	154	Altieri, D.C. J Leukoc Biol 1995, 58, 120-127.	
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	157	Lowenstein, C. J. and Snyder, S. H. in Cell 1992, 70, 705-707.	
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	159	Kirkeboen, K.A. and Strand, O.A. in Acta Anaesthesiol Scand 1999, 43, 275.	
	160	Wood, E. R. et al. in Biochem Biophys Res Commun 1993, 191, 767-74.	
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				Filing Date	September 25, 2003
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	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.	
	165	Van Molle W. et al. in J Immunol 1997, 159, 3555.	
	166	Bratt, J. and Palmblad, J. in J Immunol 1997, 159, 812.	
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	169	McCall, T.B. et al., in Biochem. Biophys. Res. Commun. 1992, 186, 680.	
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	172	Schini et al. in Circ Res 1994, 74, 24.	
	173	Meki, A. R. et al. in Toxicon 1998, 36, 18519.	
	174	Popko B. and Baerwald, K. D. in Neurochem Res 1999, 24, 331.	
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	177	Remington's Pharmaceutical Sciences, 1990, p. 1519-1675, Gennaro, A.R., ed., Mack Publishing Company, Easton, PA.	
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	179	Budavari, Susan (Editor), "The Merck Index", An Encyclopedia of Chemicals, Drugs, and Biologicals; Merck & Co., Inc., 11th edition.	
	180	Merrifield, R.B., "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", 1963, J. Am. Chem. Soc., (85):2149.	
	181	Animal Cell Culture, R.I. Freshney, ed. 1986, IRL Press, Oxford.	

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	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.	
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.	
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	185	Auerswald et al., "K15R M52E) aprotinin is a weak Kunitz-type inhibitor of HIV-1 replication in H9 cells" Biomed Biochim Acta, 1991, 50(4-6):697-700.	
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	187	Koito et al., "A neutralizing epitope of human immunodeficiency virus type 1 has homologous amino acid sequence with the active site of inter-alpha-trypsin inhibitor", 1989, Int Immunol, 1(6):613-8.	
	188	McNeely et al., "Secretory leukocyte protease inhibitor: a human saliva protein exhibiting anti-human immunodeficiency virus 1 activity in vitro", 1995, J Clin Invest, 96(1):456-64.	
	189	Hallenberger et al., "Inhibition of furin-mediated cleavage activation of HIV-1 glycoprotein gp160", 1992, Nature, 360(6402):358-61.	
	190	Vollenweider, et al., "Comparative cellular processing of the human immunodeficiency virus (HIV-1) envelope glycoprotein gp160 by the mammalian subtilisin/kexin-like convertases", 1996, Biochem. J.;314 (Pt2):521-32.	
	191	Anderson et al., "Inhibition of HIV-1 gp160-dependent membrane fusion by a furin-directed alpha 1-antitrypsin variant", 1993, J Biol Chem, 268(33):24887-91.	

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	192	Decroly, et al., "Identification of the paired basic convertases implicated in HIV gp160 processing based on in vitro assays and expression in CD4(+) cell lines", 1996, J Biol Chem, 271(48):30442-50.	
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				Application Number	10/669,250
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	15	of	17	Attorney Docket Number	330310.00103

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	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
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				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
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	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
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